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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,245	08/18/2003	David R. Fischell	MR3065-19	2995

4586 7590 08/11/2010
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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

NOTIFICATION DATE	DELIVERY MODE
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08/11/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/642,245	Applicant(s) FISCHELL ET AL.	
	Examiner George R. Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 40-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-36, 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37 and 40-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1-36 and 48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/25/09.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/9/10 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37 and 40-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is the user selected offset times being "at least one of T_{pq} or T_{st}" and the processing means assessing cardiac function "based upon the amplitude of the electrical signal at said one of said

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samples defined by the R wave and the first particular offset time” in combination with the other elements in the claim(s). Claim 37 is broadening the original scope of the invention by, at the minimum as set forth by the claim, just using one offset time and using an amplitude of a sample at an offset time to assess cardiac function. This scope was originally not set forth in the original specification and is considered new matter. The original specification dealt with determining cardiac ischemia using more elements to assess the condition of the heart, such as basing the cardiac assessment on the amplitude compared to a baseline signal/threshold (e.g. page 10 of the specification). In addition, the original specification had the physician entering both offset values, Tpq and Tst (e.g. page 11 of the specification) and not being “at least one of Tpq or Tst” as this means only one value needs to be used instead of both.

Claims 37 and 40-47 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Using two offset times and assessing cardiac function based on both the amplitude and a baseline signal/threshold are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). As discussed in the immediately preceding paragraph, using two offset times and assessing cardiac function based on both the amplitude and a baseline signal/threshold are critical/essential.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37 and 40-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 37, in the preamble, "A system using an electrical signal...measured by implantable electrodes" is vague since no "electrical signal" element is first set forth for the system to positively recite "using" the electrical signals and it is unclear if this is the same as the "means for receiving said plurality of R-R intervals". In addition, it is unclear if the applicant is positively or functionally reciting the electrodes. Lines 4-6 make the claim vague since it is further defines the electrical signal, but then the claim body after "including" uses different terms for the electrical signal. It is suggested to just state "A system for assessing cardiac function, the system comprising" so as to not inferentially include any elements, and so the cardiac signal can be defined once in the claim body (e.g. QRS, R-R intervals, etc).

In claim 37, line 8, "and corresponding to a plurality of R-R intervals" is vague. It is unclear how it "corresponds" to R-R intervals if the offset time is T_{pq} or T_{st} . In addition, "a plurality of R-R intervals" is vague and it is unclear if this is the same R-R interval used in line 5 or different intervals and it is unclear if each offset time corresponds to just one R-R interval or to a plurality of R-R intervals.

In step (b), it is unclear if the means for receiving the plurality of R-R intervals is the same as the "electrical signal" and R-R interval used in lines 1-5 of the claim. It is suggested to use the shortened preamble discussed above and/or to state that the means for receiving also receives cardiac electrical signals.

In step (d), “from an R wave of one beat of said electrical signal” is vague since it is unclear if the “R wave” is from the “R-R interval” used in line 5 or is from the “means for receiving” in step (b) and it is unclear if the “said electrical signal” is from the means for receiving of step (b) since no element has been set forth to receive an electrical signal. In step (d), line 3, “said plurality of digital samples” is vague since no element has been set forth to take digital samples. Although line 4 of the preamble states the electrical signal comprises a plurality of digital samples, no element has been set forth to take digital samples or the electrical signals. In step d, line 4, “is between the PQ and ST segments” is vague since it has not set forth which signal is being discussed to take the PQ/ST segments from. In line 6, “user selected offset times associated with the R-R interval” lacks antecedent basis as the claim has not previously set forth that the user selected offset times are “associated with the R-R interval” as the claim states the user selected offset times “corresponds to a plurality of R-R intervals” in step (a) and it is unclear if this is meant to be the “R wave” of step d, line 2, since this R-wave is used with “one beat”.

In step (e), “the amplitude of the electrical signal at said one of said samples” is vague since no element has been set forth to take a sample at that particular point in time and to determine the amplitude there. In addition, “defined by the R wave and the first particular time offset” is vague since it is unclear if this is two elements used for the assessment or whether this is one element defining the point in time to take the signal. It is suggested to state “processing means for assessing cardiac function based on the baseline signal and an amplitude of the electrical signal at the first particular offset time from the R wave”.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP

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§ 2172.01. The omitted elements are: using two offset times and assessing cardiac function based on both the amplitude and a baseline signal/threshold. It is suggested to claim an element to determine the baseline signal, such as “means for determining a baseline signal” to use in the processing means.

In claim 40, “the sample with the R wave” lacks antecedent basis as no element has been previously set forth to take a sample “within” the R wave.

In claim 41, “the sample within defined by the R-wave” lacks antecedent basis. In addition, “within an ST segment” is vague since it is unclear if this is the same ST segment used in claim 37, step d.

In claims 43 and 44, the claims are vague since they state the user selected offset times “correspond to the R-R interval” but claim 37 states that the offset times correspond to a “plurality of R-R intervals”.

In claim 45, “R waves” is vague since it is unclear which R wave is being discussed that was previously recited or whether this is to a new R wave. In line 6, “one of the plurality of user selected offset times” is vague since it is unclear if the first or the second offset time is being discussed. In line 7, “the R-R interval” is vague since it is unclear if this corresponds to the first plurality of R-R intervals used in claim 37, or corresponds to the second plurality listed in claim 45. In the last line “of the ST segment defined by the first particular offset time” lacks antecedent basis and no element has been set forth to determine the amplitude of the ST segment and to have the ST segment defined by the first particular offset time (claim 37 has not set this forth).

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571 272 4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762